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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,257	12/14/2001	Jangbir S. Sangha	CHO004/106011	8707

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EXAMINER	
FREDMAN, JEFFREY NORMAN	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/020,257	SANGHA ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-29,32-36,38,40-55,66,68-76,78-86 and 88-102* is/are pending in the application.

4a) Of the above claim(s) *7-25,40-55 and 96-102* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-29,32-36,38,66,68-76,78-86 and 88-95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status

Claims 7-29, 32-36, 38, 40-55, 66, 68-76, 78-86, 88-102 are pending.

Claims 26-29, 32-36, 38, 66, 68-76, 78-86, 88-95 are rejected.

Claims 7-25, 40-55, 96-102 are withdrawn from consideration.

Any rejection which is not reiterated in this action is hereby withdrawn as no longer applicable.

Applicant should note that this action is made Non-final due to the new 102 and 103 rejections added to the maintained 103 rejections.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 15, 2005 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 26-29, 33, 36, 38, 66, 69, 73-76, 79, 86, 89 and 93-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al (U.S. Patent 2,703,083).

As applicant is aware, a product need not share the same intended use in order to anticipate a claim. As MPEP 2114 notes, for example, "A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim." This rejection, using the Gross reference, meets the structural limitations of the claim.

Gross teaches a device of claims 26, 36, 38, comprising:

(a) a collection portion (see figure 4 and column 6, lines 55-60, where the dressing pad of the adhesive bandage (often referred to using Johnson and Johnson's trademarked name Bandaid ®) will function to collect material, and in particular, will ordinarily collect blood, where blood is clearly a material containing DNA),

The collection portion has a front and rear surface, with the rear surface having a covering thereon to prevent collection of material containing DNA and the front surface is available for collection of material containing DNA (see figure 4, where the dressing pad 42 is placed on a sheet 40 that may be composed of a nonporous material such as plastic (see column 10, lines 26-36, for example) where the pad is exposed to the wound on the front surface but the rear surface is covered as in a normal adhesive bandage),

(b) a housing for holding said device (see column 11, example 1, lines 41-44, where the adhesive bandages were wrapped in glassine paper that was sealed, where the glassine paper is a housing),

(c) a treatment applied to said housing after said housing is filled with said device, said treatment comprising an effective quantity of an agent for disabling DNA from interfering with subsequent speciment specific DNA analysis (see column 11, lines 60-70, where ethylene oxide treatment was used to sterilize the bandages).

With regard to claims 27-29, Gross teaches a device which is capable of being used on any tissue including cheek or tongue. The limitations of claims 27-29 do not impose any structural requirements on the product and simply represent intended uses of the product. As MPEP 2111.02 notes "Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." Here, no such structural difference currently exists.

With regard to claims 33, 69, 79, 89, Gross teaches ethylene oxide treatment was used to sterilize the bandages (see column 11, lines 60-70).

With regard to claim 66, 76, 86, Gross teaches a second protective layer that is foldable over the second side to prevent contamination of the second side which may even form a pouch (see figure 4, where the plastic covers of the adhesive also cover the pad and are foldable over the dressing pad 42 and see figures 9 and 10 for pouchlike form).

With regard to claim 73, 83, 93, Gross teaches a dressing pad composed of paper (see column 6, line 55).

With regard to claims 74-75, 84-85, 94-95, Gross teaches an adhesive surface (see column 6, lines 6-21 and figures 1-4, for example).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 32, 34-35, 68, 70-71, 78, 80-81, 88 and 90-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al (U.S. Patent 2,703,083) in view of Northview Biosciences Inc. (March 2001) (titled Sterility Assurance Compliance) (http://www.northviewlabs.com/pdf_docs/SterilityAssurance.pdf).

Gross teaches a device of claims 26, 36, 38 comprising:

(a) a collection portion (see figure 4 and column 6, lines 55-60, where the dressing pad of the adhesive bandage (often referred to using Johnson and Johnson's trademarked name Bandaid ®) will function to collect material, and in particular, will ordinarily collect blood, where blood is clearly a material containing DNA),

The collection portion has a front and rear surface, with the rear surface having a covering thereon to prevent collection of material containing DNA and the front surface is available for collection of material containing DNA (see figure 4, where the dressing pad 42 is placed on a sheet 40 that may be composed of a nonporous material such as plastic (see column 10, lines 26-36, for example) where the pad is exposed to the wound on the front surface but the rear surface is covered as in a normal adhesive bandage),

(b) a housing for holding said device (see column 11, example 1, lines 41-44, where the adhesive bandages were wrapped in glassine paper that was sealed, where the glassine paper is a housing),

(c) a treatment applied to said housing after said housing is filled with said device, said treatment comprising an effective quantity of an agent for disabling DNA from interfering with subsequent speciment specific DNA analysis (see column 11, lines 60-70, where ethylene oxide treatment was used to sterilize the bandages).

With regard to claims 27-29, Gross teaches a device which is capable of being used on any tissue including cheek or tongue. The limitations of claims 27-29 do not impose any structural requirements on the product and simply represent intended uses of the product. As MPEP 2111.02 notes "Intended use recitations and other types of

functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." Here, no such structural difference currently exists.

With regard to claims 33, 69, 79, 89, Gross teaches ethylene oxide treatment was used to sterilize the bandages (see column 11, lines 60-70).

With regard to claim 66, 76, 86, Gross teaches a second protective layer that is foldable over the second side to prevent contamination of the second side which may even form a pouch (see figure 4, where the plastic covers of the adhesive also cover the pad and are foldable over the dressing pad 42 and see figures 9 and 10 for pouchlike form).

With regard to claim 73, 83, 93, Gross teaches a dressing pad composed of paper (see column 6, line 55).

With regard to claims 74-75, 84-85, 94-95, Gross teaches an adhesive surface (see column 6, lines 6-21 and figures 1-4, for example).

Gross does not teach modes of sterilization other than ethylene oxide.

Northview Biosciences teaches sterilization of kits using a variety of equivalent techniques including ethylene oxide, gamma radiation and electron beam radiation (see page 2), addressing the limitations of claims 32, 34-35, 68, 70-71, 78, 80-81, 88 and 90-91.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to sterilize the bandages of Gross using any of the known means taught by Northview Biosciences since Northview Biosciences notes "Sterility is essential to the safety of many medical devices. Most single use devices are terminally sterilized by ethylene oxide gas or gamma or electron beam radiation (see page 2)". An ordinary practitioner would have been motivated to sterilize using known equivalent methods of sterilization in order to ensure that the single use bandages are terminally sterilized. Further, MPEP 2144.06 notes " Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout , 675 F.2d 297, 213 USPQ 532 (CCPA 1982)." Here, the different modes of sterilization are expressly recognized by the prior art as known equivalents for the same purpose.

7. Claims 26-29, 32-36, 38, 66, 68-76, 78-86 and 88-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ricciardi et al in view of Furcht et al (U.S. Patent 6,303,288) in view of Northview Biosciences Inc. (March 2001) (titled Sterility

Assurance Compliance)

(http://www.northviewlabs.com/pdf_docs/SterilityAssurance.pdf).

Ricciardi et al teaches a kit for the collection of material containing DNA (see abstract and figure 1) comprising:

(a) a housing containing at least one collection device for collection material containing DNA (see figure 1 and column 2, lines 30-42).

Ricciardi expressly teaches that the swabs may be used for PCR amplification and that the swabs should be sterile (see column 2, lines 5-10).

With regard to claim 56, Ricciardi teaches a tubular holder, see figure 1, hole 30a, which is tubular shaped and which permits extension and retraction through the holder (see figure 1).

With regard to claims 62-64, Ricciardi teaches the use of Dacron swabs which have some level of adhesion that is variable in it's binding (see column 3, lines 36).

Ricciardi et al does not teach modes of sterilization.

Northview Biosciences teaches sterilization of kits using a variety of equivalent techniques including ethylene oxide, gamma radiation and electron beam radiation (see page 2)

With regard to claims 76 and 86, Ricciardi teaches placement of the swabs in a protective pouch (see figure 1).

With regard to claims 32-35, 39, 68-71, 78-81, 88-91, Northview Biosciences teaches sterilization of kits using a variety of equivalent techniques including ethylene oxide, gamma radiation and electron beam radiation (see page 2)

Ricciardi et al in view of Northview Biosciences Inc. do not teach a device which has a rear surface that prevents collection of the DNA.

Furcht et al teaches, with regard to claims 26, 36, 38, 66, a device for the collection of material containing DNA (see abstract and figure 1) comprising:

A device for collecting material containing DNA that has a collection portion, (figure 3, reference number 32, which column 8, lines 54-67 identifies as a sample collection pad that is placed on a plastic support, reference number 31 (see column 8, lines 41-44), where the figure shows a front surface that is available for the collection of material containing DNA and a rear surface that is covered by plastic and is not available for DNA collection (see figure 3).

With regard to claims 27-29, Furcht teaches buccal scraping (see column 8, line 62). Further, these limitations do not impose any structural requirements on the product and simply represent intended uses of the product. As MPEP 2111.02 notes "Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." Here, no such structural difference currently exists.

With regard to claims 65, 72-75, 82-85, 92-95, Furcht teaches the use of FTA paper which inherently has some level of adhesion that is at least slightly variable in it's binding (see column 8, line 58).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the device of Furcht in the kit of Ricciardi since Furcht notes "This application of the microcantilever based sensor offers superior sensitivity, specificity and utility in an integrated MEMS system format (see column 12, lines 7-10)." Furcht further motivates the use of FTA paper by noting "DNA extractions on FTA^{tm} paper have demonstrated significant ease in use and reduced cost in performing routine clinical molecular genetic testing (see column 2, lines 53-56)." Motivation to sterilize the device is provided by Northview Biosciences which notes "Sterility is essential to the safety of many medical devices. Most single use devices are terminally sterilized by ethylene oxide gas or gamma or electron beam radiation (see page 2)". An ordinary practitioner would have been motivated to use the device of Furcht in the kit of Ricciardi since the device will improve sensitivity, specificity and utility and reduce labor costs and specimen sizes (see column 12 and column 2, lines 21-38). Further, an ordinary pracititioner would have been motivated by Northview biosciences to sterilize the kit in order to improve the safety of the device and to ensure that swabs, which would be placed within the oral cavity of human beings, would not contain any hazardous materials such as pathogenic microorganisms or viruses.

Response to Arguments

8. Applicant's arguments filed August 15, 2005 have been fully considered but they are not persuasive.

Applicant argues that the Furcht genestrip is not itself a DNA collection device. This is not relevant since the intended use does not structurally impact the device. So

long as the device is sufficiently small to meet the implicit requirements of the claim, ie fit inside a person's mouth, the teaching is sufficient to meet the structural limitations of the claim. As noted above, MPEP 2114 notes, for example, "A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim."

Each of Applicant's points regarding the Furcht device go to function, not structure. There is no structural difference imposed by the claims which distinguishes the Furcht device and it is structural limitations, not functional limitations, which are at issue. Further, these points are not persuasive even as written. (1) With regard to size, the size of the device is optimizable. The argument that the device would not function as a buccal swab is incorrect since PCR is capable of detecting a single cell and the pad is of more than sufficient size to obtain thousands of cheek cells. (2) With regard to the issue of whether the pad should be placed in the cheek, this is expressly a functional limitation on a product claim. There is no structural requirement that the device be placed into a cheek. Placement of the swab of cheek cells onto the FTA paper achieves the same goal, and meets the claim requirements. Since Furcht expressly teaches placement of material which is comprised of cheek cells onto the FTA paper, even if indirectly, Furcht remains applicable in the obviousness rejection.

Finally, Applicant is expressly claiming FTA paper. Since the negative teaching regarding FTA paper upon which Applicant is relying is not drawn from either Furcht or Ricciardi, the teaching would seem equally applicable to Applicant's own claims and

suggest that these claims are nonenabled. However, because the evidence is not persuasive, in the interests of consistency, no enablement rejection will be applied to the claims. If Applicant brings in direct evidence, rather than inference piled on inference, that FTA paper has been shown to be unusable in buccal swabs, the claims at issue will be subject to an enablement rejection.

Applicant heavily relies upon the preamble language "a device for selective collection". With regard to preamble language in apparatus claims, the MPEP and caselaw are very clear that only structural limitations, not functional limitations, will overcome prior art that is structurally identical or prima facie obvious. That is the current situation and the arguments do not overcome the cited prior art. As Applicant will also note, additional prior art rejections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jeffrey Fredman
Primary Examiner
Art Unit 1637